

Application No. 09/545,334
Amendment Dated: December 16, 2004
Reply to Office Action of June 16, 2004

REMARKS

Claims 1, 17, 64, and 65 have been amended to replace "nontransgenic siblings" with "a control plant." Support for this amendment can be found in the specification, for example at page 15, lines 27-32, and at page 36, line 34.

Claims 1 and 17 have been amended to delete the word "fertile". Support for this amendment can be found in the specification, for example at page 52, lines 1-2, and at page 55, lines 10-11. This amendment is made consistent with the disclosure in that regenerated plants, and/or their progeny, may be less than fully fertile, e.g. male-sterile or female-sterile.

Claims 1, 17, 30, 43, 64, and 65 have been amended to claim methods and constructs comprising a polynucleotide encoding an isopentenyl transferase. Support for this amendment can be found in the specification, for example at page 21, line 6, through page 22, line 12.

Claims 43-47 are amended as to the timing of expression. Support for this amendment can be found in the specification, for example at page 6, line 13; page 7, line 1; and page 29, lines 18-23.

Rejection under 35 USC 112, enablement

The Examiner has rejected Claims 1-4, 7-8, 10, 17, 20-21, 23, 30, 32-33, 35, 42-47, and 64-65 for lack of enablement. The Applicants respectfully traverse the rejection.

The Examiner contends that "given the unpredictability in using any cytokinin modulating enzyme in any plant as stated in the office action dated 3/37/2003, undue trial and error experimentation would be required to practice the claimed invention."

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with

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information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

Pursuant to the amendments made 4/19/04 and in this current Response, in an effort to expedite prosecution, Applicants are specifically claiming "an isopentenyl transferase." Applicants reserve the right to pursue unclaimed subject matter in continuation or divisional applications. Consistent with those claims, Applicants ask that the enablement rejection as to "any cytokinin modulating enzyme" be withdrawn.

The claimed invention provides novel constructs comprising a polynucleotide encoding an isopentenyl transferase operably linked to specific promoters, and novel methods of use of said constructs to create improved plants. The sequence listing (e.g. SEQ ID NO: 7) provides the sequence of an *ipt* gene isolated from *Agrobacterium tumefaciens* (Strabala et al. (1989) *Mol. Gen. Genet.* 216:388-394). The specification states, with reference to polynucleotides encoding cytokinin biosynthetic enzymes, that polynucleotides other than those provided in the sequence listing may be used in the invention:

Particularly preferred embodiments in this respect, moreover, are polynucleotides which encode polypeptides which retain substantially the same, or even exhibit an increase in, biological function or activity as the mature polypeptide encoded by the polynucleotides set out below. (specification, p. 22)

There is no requirement for Applicant to discover or disclose every possible species within the claimed genus. It is well within the knowledge of a person of skill in the art to substitute homologous or analogous genes to achieve the desired result. The invention encompasses use of "a polypeptide which retains essentially the same biological function or activity" (p. 25, lines 6-7), including a synthetic polypeptide (p. 25, line 14). Clearly, the *function* of the encoded polypeptide is the common element, and the biological or chemical *source* is not critical.

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A person of skill in the art, provided with the disclosure of this application, would recognize that alternative isopentenyl transferase genes could be used. In fact, *ipt* genes have been identified in plant species. See, for example, co-pending 60/610,656 filed September 17, 2004 (maize); Takei et al. (2001) J. Biol. Chem. 276:26405-26410 (Arabidopsis); Zubko et al. (2002) Plant J. 29(6):797-808 (petunia); Sakano et al. (2004) Phytochem. 65:2439-2446 (hop); and GenBank accession XM_477138 (rice, 2004). Therefore, to require the Applicants to limit claims to bacterial *ipt* genes when an equivalent was entirely foreseeable, and now clearly available, would be inappropriate in light of recent case law (*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359 (Fed. Cir. 2003) (*en banc*)). Such a limitation would allow others to avoid the claims by using the present application as a template and merely substituting an isopentenyl transferase isolated from a non-bacterial source.

The Examiner further states that "any plant" is not enabled.

Applicants respectfully traverse. While the specific examples provided in the application are directed to transformed maize, the specification provides that the methods and constructs of the invention may be used in a variety of species. See, for example, page 32, lines 21-31, and the following:

Hosts for a great variety of expression constructs are well known, and those of skill will be enabled by the present disclosure readily to select a host for expressing a polypeptide in accordance with this aspect of the present invention.
(specification, page 32, lines 32-34)

To fulfill the enablement requirement, "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993). (emphasis added) Nor is it necessary to provide "production specifications" covering every detail in order to meet the enablement

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requirement. *In re Gay*, 309 F.2d 769, 774, 50 CCPA 725, 733, 135 USPQ 311, 316 (CCPA 1962).

A person of skill in the art, upon reading the present disclosure, would be equipped to apply the claimed methods to other plant species. Appropriate transformation techniques were well known in the art at the time the application was filed. For example, successful transformation and plant regeneration had previously been reported in rice (Tanaka et al. (1990) *Nucleic Acids Res.* 18(23):6767-6770), sorghum (Hagio et al. (1991) *Plant Cell Reports* 10(5):260-264), sunflower (Bidney et al. (1992) *Plant Molecular Biology* 18(2):301-314), barley (Batty et al. (1992) *Transgenic Research* 1(3):107-113), soybean (Bailey et al. (1993) *In Vitro Cellular and Developmental Biology of Plant* 29P(3):102-108), wheat (Weeks et al. (1993) *Plant Physiology* 102(4):1077-1084), oat (Torbert et al. (1995) *Plant Cell Reports* 14(10):635-640), and *Phaseolus* and *Vigna* genera (Nagl et al. (1997) *Journal of Plant Physiology* 150(6):625-644).

In light of the amendments and remarks made herein, Applicants respectfully ask that all rejections as to enablement be withdrawn.

Rejection under 35 USC 112, Written Description (per Office Action of 12-17-03)

The Applicants note that the Examiner previously stated (O.A. of 12/17/03, pp.6-7) that "Applicants have fulfilled the written description requirement for bacterial ipts but not for all ipts, including plant ipts." The Examiner further states that "Applicants fail to describe a representative number of ipts encoding nucleic acid molecules from plants which fall within the scope of the claimed ipt genus." (O.A. 12/17/03, p. 7)

Applicants traverse and will address this rejection at this time.

The Examiner has cited *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ1d 1398, 1406 (Fed. Cir. 1997). The Federal Circuit has since refined its position on written description. Referring to the PTO Guidelines

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for Written Description Examination (66 Fed. Reg. at 1106), the Federal Circuit noted in *Enzo Biochem Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In the present case, Applicants have provided adequate support for the genus of *ipt* genes. First, a known *ipt* gene is identified by its structure, both by including it in the sequence listing (see SEQ ID NO: 7, 8, 9, and 12) and by providing appropriate references (specification, page 3, lines 18-19; and page 16, lines 31-33). Second, the function of isopentenyl transferase in a rate-limiting step of the cytokinin biosynthetic pathway was known to a person of skill in the art at the time the application was filed (see specification, page 3, lines 8-17; see also Morris et al. (1993) *Aust J. Plant Physiol.* 20(4-5):621-637 and Beaty et al. (1986) *MGG* 203(2):274-280). Third, sequences suitable for use in the claimed methods are correlated to the identified sequence in terms of hybridization (specification, page 22, line 13, through page 23, line 36) and degree of sequence similarity (specification, page 21, line 6, through page 22, line 12). Applicants further point out that the claims are not drawn to a genus of *ipt* genes themselves, but to methods of use of constructs comprising said sequences to achieve specific plant phenotypes. Thus, description which includes a functional element is appropriate.

In light of the amendments and remarks herein, Applicants respectfully ask that all rejections as to written description be withdrawn.

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Rejection under 35 USC 102, Anticipation

Claims 1-2, 4, 17, 30, 42-43, and 64-65 are rejected under 35 USC 102(b) as being anticipated by Houck et al. (5,177,307).

Applicants respectfully traverse. "For a prior art reference to anticipate in terms of 35 U.S.C. Section 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 15 USPQ 2d 1566 (Fed. Cir. 1990).

Specifically, the Examiner states that:

"..Houck et al teach the exact method steps which comprise transforming a plant with the same IPT gene under the control of a promoter that expresses in developing fruits, which are part of 'related maternal tissues', and seeds." (O.A. 6/16/04, p. 5)

Applicants respond that the constructs and methods of the present application are distinct from those disclosed by Houck et al. Houck et al. is directed to manipulation of cytokinin expression to affect fruits, in particular, the tomato fruit to which the claims of '307 were limited. Houck et al. does not disclose manipulation of cytokinin expression to affect seed size, seed abortion, or seed set.

The Examiner states that Houck et al. use "a promoter that expresses in developing fruits, which are part of 'related maternal tissue', and seeds." (O.A. 6/16/04, p. 5, lines 5-6)

The Applicants respectfully ask the Examiner to point out with particularity where Houck et al. describe their invention as encompassing use of "a promoter that expresses in... seeds." The Applicants maintain that Houck et al. never disclose nor claim expression of ipt in any tissue other than ovary wall. The patent describes manipulation of cytokinin expression to affect fruit development, but not affecting seed size, seed abortion, or seed set.

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The Examiner further states:

"Therefore, given that the method steps are the same as Applicants', given that the constructs are the same as Applicants', and given that the plant population is the same as Applicants' claimed invention, it must by necessity have the same outcome." (O.A. 6/16/04, p. 5)

Applicants respectfully traverse. As pointed out above, the Applicants' constructs are distinct from those of Houck et al. In addition, the outcome obtained by the claimed constructs and methods is clearly distinct from the outcome obtained by Houck et al. For example, Figure 2 of Houck et al. shows significant zeatin changes in ripening fruit tissues. This is the intent of Houck et al.:

"Of particular interest to modify are tissue specific characteristics, such as those relating to handling of botanical fruit, for example, the total solids content of ripe fruit, improved retention of early fruit, and time of onset of ripening."
(Col. 3, bottom)

The Examiner cites *Integra LifeSciences I Ltd. V. Merck KGaA*, 50 USPQ2d 1846, 1850 (DC SCalif 1999), for its teaching that "where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method."

Applicants respectfully respond that, as set forth above, the cited art *neither* teaches all of the required steps of the claimed method *nor* produces the claimed result.

Even if the claimed method were anticipated, the statute and case law provide ample support for the patentability of a new use of a known process:

35 USC 100(b): The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

35 USC 101: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful

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improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Examiner has stated :

"It would be an inherent feature of seeds in which cytokinin levels is modulated, that the stress tolerance and yield stability would be improved and as such, Houck et al anticipate the claimed invention." (O.A. 3/27/03, p. 14, lines 1-3)

Numerous cases have established that a forward chronology is used to determine whether inherency exists. That is, one looks first to the prior art disclosure and asks whether that disclosure necessarily always results in the claimed invention. For example:

"[I]f a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process will be considered to have been anticipated by the former patented device."
In re Ackenbach, 45 F. 2d 437, 439; 7 USPQ 268, 270 (CCPA 1930)

The Courts have noted that it would be inappropriate to *assume* that the previously patented device performs the claimed function:

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."
In re Robertson, 169 F.3d 743; 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Where, as here, the reference patent Houck et al. does not disclose the claimed plants with improved seed size, decreased seed abortion and increased seed set, nor the method by which to obtain such plants, and in light of the numerous later publications by others in the art specifically reporting no seed mass increase, as previously cited by Applicant (Response 4/19/04, p. 12), the extrinsic evidence necessary to support a finding of inherency does not exist.

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In light of the amendments and arguments made herein, Applicants respectfully ask that the Examiner withdraw all rejections under Section 102.

Rejection under 35 USC 103, Obviousness

Claims 1-4, 8, 10, 17, 21, 23, 30, 33, 35, 42-47, and 64-65 are rejected under 35 USC 103(a) as being unpatentable over Houck et al. (US 5,177,307) in view of Tomes (US 5,877,400). Applicants traverse the rejection.

The Examiner states that the Applicants' method claims all "comprise the same method step which is the introduction of an IPT gene into a plant" and that "the Houck et al reference teaches the exact method step."

Applicants reiterate, as pointed out in detail above, that the methods differ in that expression is directed towards different plant tissues, with significant impacts on results. Houck et al. *do not disclose* positive effects on seed production as a result of their methods.

The Examiner points specifically to the '400 patent as teaching "other promoters, embryo and endosperm expressing promoters known in the art prior to Applicants' filing date."

Applicants note that the '400 patent is directed to

"...transgenic plants, seeds, and tissues which have been genetically modified to create plants that will bypass the need for fertilization and ... will produce seedless fruits and vegetables..." (emphasis added)

Applicants respectfully ask that the Examiner point out the motivation within these patents to combine a method of producing seedless fruits ('400) with a method of affecting fruit growth ('307), to arrive at a method for improved seed size, decreased seed abortion or increased seed set during unfavorable environmental conditions. As stated in MPEP 2141.01, when applying 35 U.S.C. 103, "The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination."

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Furthermore, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01, citing *In re Gordon*, 733 F.2 900, 221 USPQ1125 (Fed. Cir. 1984). In the present case, substituting embryo or endosperm promoters for the ovary-wall-specific promoters of Houck et al. would eliminate the desired effect on fruit production. Thus there is no suggestion or motivation to combine.

The Examiner states at page 7 (O.A. 6/16/04), "In regards to 'mass of seeds which improves seed set and increases yield', Applicant is arguing limitations not specified in the claims."

Applicants respond that the quoted phrase is not Applicants' statement; it was made by the Examiner in the Office Action of 12/17/03, page 12, lines 6-7, in characterizing 5,177,307. Applicants merely repeated the Examiner's statement as a preface to the arguments thereto in the Response of 4/19/04 (pp. 13-14). Applicants maintain that the Examiner's characterization is unsupported and would ask the Examiner to point out with particularity the basis for such statement.

The Examiner also states at page 7, "the 'superficial' disclosure of senescence is still a disclosure of senescence and is applicable in regards to the normal decline and death of a plant or the end result of an unfavorable environment." The Examiner is referring to column 3, lines 3-5, where Houck et al. allude to the modulation of cytokinin concentrations to delay senescence.

Applicants respond that, as detailed in the response to the 102 rejection above, Houck et al. is directed to manipulation of cytokinin in fruit tissues. Applicants note that Houck et al. further refer to senescence at column 9, lines 36-59, with respect to delaying or promoting fruit maturation. There is no motivation to combine Houck et al., which discloses modification of fruit ripening, with Tomes, which discloses methods of producing seedless fruit, to arrive at claims for plants

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with improved seed size, decreased seed abortion or increased seed set during unfavorable environmental conditions.

Applicants therefore respectfully ask that the Examiner withdraw the rejections under Section 103.

CONCLUSION

Fees for extension of time are provided for in documents accompanying this paper. It is believed that, as there is no net addition of claims, no excess claims fees are due. However, in the event that additional fees are necessary to allow consideration of this paper, such fees, as well as fees for extension of time, are hereby authorized to be charged to Deposit Account # 16-1852 as shown on the enclosed Fee Transmittal.

Applicants believe that all claims under consideration are in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

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